

Original article

Prevalence and Prognosis of High-risk Myocardial Infarction Patient Candidates to Extended Antiplatelet Therapy



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Article history:

Received 28 September 2015

Accepted 18 December 2015

Available online 7 April 2016

Keywords:

Myocardial infarction
Prognosis
Epidemiology
Follow-up studies
Diabetes mellitus
Coronary disease
Survival

ABSTRACT

Introduction and objectives: Secondary prevention in myocardial infarction patients is paramount to prevent recurrences. Dual antiplatelet therapy has been shown to reduce the risk of subsequent events up to 1 year and beyond in the PEGASUS-TIMI 54 trial. This study aimed to estimate the annual number of myocardial infarction patients with PEGASUS characteristics in Spain and to analyze short- and long-term outcomes in these patients.

Methods: The number of myocardial infarction patients was estimated assuming a Poisson distribution. Myocardial infarction incidence and mortality rates obtained from population registries (IBERICA and REGICOR) were properly adjusted. The proportion of myocardial infarction patients with PEGASUS characteristics was estimated with a REGICOR cohort of consecutive patients from 2003-2009 (n = 1391). This cohort follow-up was used to compare the occurrence of reinfarction and death at 1 year and at the end of the follow-up (4.7 years) in patients with and without PEGASUS characteristics by Cox regression.

Results: The estimated annual number of stable myocardial infarction patients aged ≥ 50 years and without bleeding events was 41 311. Of these, 22 493 had at least 1 PEGASUS characteristic (diabetes, previous myocardial infarction, or chronic kidney disease). At 4.7 years of follow-up, having any PEGASUS characteristic or age ≥ 65 years was associated with a higher risk of cardiovascular and all-cause death in adjusted analyses (hazard ratio = 3.44 and 2.21, 95% confidence interval, 1.22-9.74 and 1.11-4.42, respectively).

Conclusions: In Spain, more than 50% of the stable myocardial infarction patients aged ≥ 50 years are estimated to have at least 1 PEGASUS characteristic, which substantially increases the long-term risk of cardiovascular and all-cause death.

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Prevalencia y pronóstico de los pacientes con infarto de miocardio de alto riesgo candidatos a doble tratamiento antiagregante prolongado

RESUMEN

Introducción y objetivos: Para los pacientes con infarto de miocardio, la prevención secundaria es de crucial importancia para evitar las recidivas. En el ensayo PEGASUS-TIMI 54 se ha demostrado que el doble tratamiento antiagregante plaquetario reduce el riesgo de episodios posteriores a lo largo de un periodo de hasta 1 año y también después. El presente estudio tiene como objetivo estimar el número anual de pacientes con infarto de miocardio que presentan las características de los pacientes del estudio PEGASUS en España y analizar la evolución clínica de este tipo de pacientes a corto y largo plazo.

Métodos: El número de pacientes con infarto de miocardio se estimó asumiendo una distribución de Poisson. Se ajustaron adecuadamente las tasas de incidencia y mortalidad por infarto de miocardio obtenidas de 2 registros poblacionales (IBERICA y REGICOR). Se estimó el porcentaje de pacientes con infarto de miocardio que mostraban las características de los del estudio PEGASUS utilizando para ello una cohorte del registro REGICOR formada por pacientes consecutivos del periodo 2003-2009 (n = 1.391). Se utilizó el seguimiento de esta cohorte para comparar, al cabo de 1 año y al final del periodo de seguimiento (4,7 años), la frecuencia de reinfartos y muertes entre los pacientes que tenían las características PEGASUS frente a los que no utilizando regresión de Cox.

Resultados: Se estimó que el número anual de pacientes con infarto de miocardio estable de edad ≥ 50 años que no presentaron episodios hemorrágicos fue de 41.311. De ellos, 22.493 cumplían al menos una de las características del PEGASUS (diabetes mellitus, infarto de miocardio previo o enfermedad

Palabras clave:

Infarto de miocardio
Pronóstico
Epidemiología
Estudios de seguimiento
Diabetes mellitus
Enfermedad coronaria
Supervivencia

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renal crónica). A los 4,7 años de seguimiento, tener alguna de las características o edad ≥ 65 años se asoció a mayor riesgo de muerte por causa cardiovascular o por cualquier causa en los análisis ajustados (*hazard ratio* = 3,44; intervalo de confianza del 95%, 1,22-9,74 y *hazard ratio* = 2,21; intervalo de confianza del 95%, 1,11-4,42 respectivamente).

Conclusiones: Se estima que en España más del 50% de los pacientes con infarto de miocardio estable de edad ≥ 50 años presentan como mínimo una de las características del PEGASUS, lo cual aumenta sustancialmente su riesgo de muerte por causa cardiovascular y por cualquier causa a largo plazo.

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Abbreviations

ACE: angiotensin-converting enzyme
 AMI: acute myocardial infarction
 ARB: angiotensin receptor blocker
 CHD: coronary heart disease
 CKD: chronic kidney disease
 DAPT: dual antiplatelet therapy

INTRODUCTION

Coronary heart disease (CHD) is the single most common cause of death in Europe, and acute myocardial infarction (AMI) is its major contributor. In Spain, nearly 100 000 individuals have an AMI each year, and 33% die before reaching a medical facility.¹ For hospitalized AMI patients, 28-day case-fatality is 13%,¹ and for those surviving the first 28-days, 2-year coronary event incidence is 12.6%.²

Aspirin effectively prevents recurrences in patients with a prior coronary event. Dual antiplatelet therapy (DAPT), with aspirin and P2Y₁₂-inhibitors (eg, clopidogrel, prasugrel, ticagrelor) further reduces the risk of subsequent coronary events in high-risk patients up to 1 year.^{3–6} Recently, the PEGASUS-TIMI 54 trial showed that aspirin + ticagrelor beyond 1 year reduced the primary combined end point of cardiovascular death, AMI, or stroke in AMI patients but increased the risk of major bleeding.⁷

Patients included in the PEGASUS trial were stable AMI patients aged 50 years and older, with at least 1 of the following risk factors: diabetes, a second previous AMI, multivessel CHD, chronic kidney disease (CKD) or age ≥ 65 years.⁸ Due to the scarcity of data on stable AMI patients and the effectiveness of aspirin + ticagrelor in high-risk AMI patients, it would be useful to determine how many AMI patients could benefit from this therapy beyond the first year after the event and to identify the long-term risk of these patients.

In the present study, we aimed first to estimate the annual number of stable AMI patients with PEGASUS characteristics in Spain. Secondly, we aimed to compare, in stable AMI patients with and without PEGASUS characteristics, the risk of AMI and death during the second year after the index AMI, and at the end of the follow-up (4.7 years).

METHODS

Study Design

To estimate the annual number of stable AMI patients with PEGASUS characteristics, we used data from 2 population-based AMI registries: IBERICA,⁹ conducted in 1997-1998 in 7 Spanish

regions, and REGICOR,¹⁰ conducted in 1990-2009 in Girona province.

Patients with AMI were classified as having PEGASUS characteristics if they were ≥ 50 years old and had previous AMI, diabetes or CKD, or were at least 65 years old. Multivessel CHD was not taken into account because the information was missing for 60% of the patients. Previous AMI was based on clinical history and information reported in standardized questionnaires. Diabetes was based on clinical history, treatment, and fasting glucose value > 6.9 mmol/L (125 mg/dL). Chronic kidney disease was based on the estimated glomerular filtration rate (< 60 mL/min/1.73m²), calculated with the Modification in Diet in Renal Disease formula.

For the comparison of short- and long-term outcomes in stable AMI patients with and without PEGASUS characteristics, we used a cohort study of consecutive AMI patients aged 35-74 years included in the REGICOR reference hospital in 2003-2009. To obtain a population of stable AMI patients similar to the population of the PEGASUS trial, we excluded patients younger than 50 years, patients who died or had a subsequent AMI in the year following the index event, patients with end-stage CKD (estimated glomerular filtration rate < 15 mL/min/1.73 m²), patients who were classified at a very high risk of bleeding by the CRUSADE risk score, and patients with history of ischemic or nonclassifiable stroke (before the AMI and during the first year post-AMI). We also excluded patients for whom the PEGASUS category could not be defined. Baseline was defined as the index AMI date plus 1 year, and thus, the follow-up to determine the occurrence of cardiovascular events and death began 365 days after the index AMI.

The REGICOR study complies with the Declaration of Helsinki and was approved by the local ethics committee. All AMI patients included were duly informed and signed a consent form to participate in the registry.

Outcomes and Variables for Prognosis Analysis

The incidence of AMI, cardiovascular death, noncardiovascular death, all-cause death, and the composite AMI/all-cause death was analyzed at 1 year and at a median of 4.7 years of follow-up in PEGASUS and non-PEGASUS stable AMI patients. The self-reported incidence of stroke was only examined in the crude analysis, as the information was only available for 43% of the included patients.

The variables used for descriptive and/or adjustment purposes were age, sex, hypertension (based on clinical history, treatment, and observed systolic/diastolic blood pressure $> 140/90$ mmHg), hypercholesterolemia (based on clinical history, treatment, and observed total-cholesterol > 200 mg/dL), smoking (smokers were defined as persons currently smoking or quitting < 1 year previously), history of angina, heart failure (based on the New York Heart Association functional classification and considered if II-IV), ST-segment elevation, angiography, reperfusion (including thrombolysis and percutaneous coronary intervention), post-AMI arrhythmia (including ventricular fibrillation and tachycardia),

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